REMARKS/ARGUMENTS

The foregoing amendments have been made and have been submitted with a Request for Continued Examination in lieu of an appeal brief. The specification has been amended to, where appropriate, refer to the "guidewire" instead of "catheter". The device was inconsistently described in different parts of the written description and where the hypotube forms a function of a guidewire by enabling a catheter to be advanced onto and along the guidewire, the amendment is made in the interest of consistency.

The claims have been amended to define further that the hypotube has an outer diameter dimensioned to enable the therapeutic catheter to be advanced onto and along the guidewire. Claim 15 has been similarly amended and includes further limitations to the expanded and low profile configurations of the distal protection device and the coupling of the hydraulic arrangement with the distal protection device such that operating the master actuating member will cause the distal protection device to return to its low profile configuration. A similar amendment has been made to claim 24.

CLAIM REJECTIONS - 35 U.S.C. §102

Reconsideration is requested of the rejection of claims 1-3, 5-17, 19-25 and 27-34 as anticipated by Kimmell patent 3,952,747. Kimmell is directed to a device for deploying a filter in a blood vessel by delivering the filter to the region where it is to be deployed and then ejecting the filter to release it into the blood vessel. The device and the filter are illustrated in FIGS. 1, 4 and 5, reproduced below.

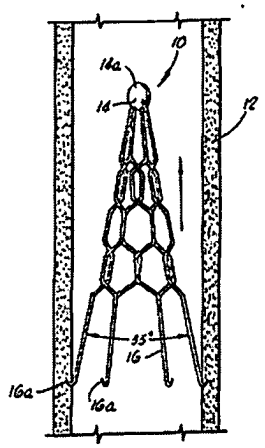

FIG. 1

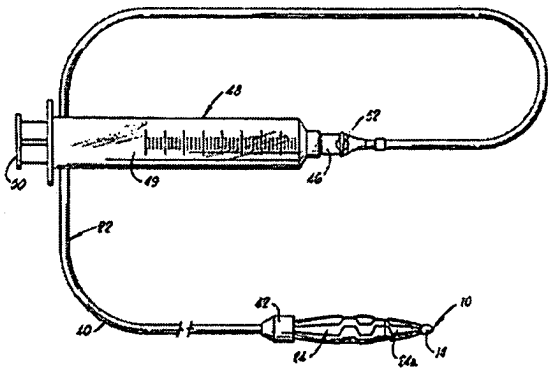

FIG. 4

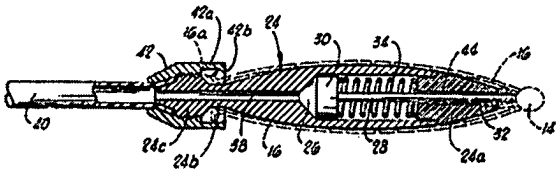

FIG. 5

The filter is placed in the vena cava to prevent blood clots from migrating into the pulmonary circulation. (1:11-25). Once the filter has been ejected from the delivery device, its legs spring outwardly to assume a generally conical configuration and hooks at the ends of the

legs bite into and impale the walls of the blood vessel to secure the filter in place (FIG. 1). (3:53-61).

The device includes an ejector assembly 28 (FIG. 5) that holds the filter in a low profile, delivery configuration in readiness to be released and deployed in the vena cava. The ejector assembly is operated hydraulically by a syringe 48. As is apparent from Kimmell, the syringe 48 "...is of conventional construction ..." (6:56-59). The hydraulic system is actuated by first connecting the outlet fitting of the syringe with a fitting 46 at the proximal end of the catheter and then depressing the plunger 50. No part of the plunger, of course, enters into the lumen of the catheter 40 or the fitting 46. The plunger 50 remains entirely within the barrel of the syringe. That is conventional syringe construction. The catheter and syringe are separate, distinct elements.

Applicant's invention relates to a guidewire for guiding a catheter to an intravascular location. The distal end of the guidewire also includes a distal protection device. As explained in the written description, the distal protection device may be deployed, temporarily during the operation of the catheter, to prevent emboli from being carried downstream from the treatment site. To further clarify the nature of the invention, claim 1 has been amended to require that the hypotube is dimensioned to enable a therapeutic catheter to be advanced onto and along the guidewire. Claim 1 also requires the hypotube guidewire to include slave and master actuating members with the master actuating member having a portion disposed within the proximal portion of the lumen of the hypotube.

To the extent that the rejection relies on Kimmell as disclosing a hypotube, that is incorrect. Kimmell makes no mention of hypotubing. It merely refers to the catheter 40. Additionally, to the extent that the rejection is based on the notion that the syringe 48 is part of a "hypotube", that is considered to be an unreasonable and arbitrary interpretation. Hypotubes are well known in the art and have a commonly understood meaning. A syringe and a catheter are separate elements with the syringe typically being substantially larger in diameter than the catheter with which it is used. Neither is reasonably considered as being hypotubing". Additionally, Kimmell does not disclose a guidewire, much less a guidewire in the form of a hypotube having an outer diameter dimensioned to enable a therapeutic catheter to be advanced onto and along the guidewire. To the extent that the rejection is based on the premise that the syringe is part of the catheter, that would be inconsistent with a guidewire function. Another

catheter could not be advanced over either or both the syringe and the catheter 40. The simple answer is the obvious, that Kimmell does not disclose a guidewire, does not disclose a hypotube and does not disclose a guidewire capable of enabling a therapeutic catheter to be advanced onto and along the device.

Reconsideration also is requested of the rejection of claims 2, 3 and 5-14. Each of those claims depends directly or indirectly from claim 1 and is not anticipated for the same reasons. Additionally, a number of those claims recite additional limitations that provide further basis for distinguishing over Kimmell including:

- a slave actuating member movable within the lumen of a hypotube (claim 2);
- where, under the theory of the rejection in which the syringe is part of a "hypotube" the lumen of the syringe is considerably larger than that of the catheter 40;
- a device in which the first plunger extends into the proximal end of the lumen of a hypotube (claim 5);
- slave actuating member with a second plunger telescopically movable in the lumen of the hypotube and extending beyond the distal end if the hypotube (claim 6);
- a slave actuating member in the form of a tube that telescopes and extends over the distal end of the hypotube (claim 7);
- a distal protection device in the form of an expandable occluder (claim 9);
- a second plunger having a sealing member to provide a seal with the hypotube (claim 10);
- a sealing member associated with a device as defined in claim 7 to provide a seal between the hypotube and the second tubular member (claim 11);
- a filter in which the proximal region has a plurality of openings. Kimmel discloses only a single opening through which emboli may pass. The remainder, downstream portion of Kimmell is intended to trap the emboli (claim 12);
- a filter with a distal region in the form of a mesh (claim 14).

Kimmel fails to disclose these features.

Claim 15 has similar limitations to those discussed above in connection with claim 1. Additionally, claim 15 includes the limitation that the self-expanding distal protection device is

adapted to self-expand from a low-profile configuration and is coupled to the distal end of the hypotube and the slave actuating member so that actuation of the master will cause the distal protection device to be returned to its low profile configuration. Kimmell does not disclose a device in which a filter can be deployed and contracted. In Kimmell, the filter is released and remains in the blood vessel. The delivery device cannot be actuated to return the filter to its low profile delivery configuration.

Claims 16-23 depend directly or indirectly from claim 15 and are not anticipated by Kimmell for the same reasons. Additionally, these claims include further limitations that distinguish over Kimmell as discussed above in connection with the claims dependent from claim 1.

Claim 24 similarly has been amended to require the hypotube to have an outer diameter to enable a catheter to be advanced onto and along the guidewire. The claim also has been amended to include the limitation of the distal protection device being self-expanding from a low profile and being coupled to the slave actuating member and hypotube so that actuation causes the distal protection device to move in a direction to collapse it to its low profile. As discussed above, these features are not disclosed in Kimmell.

Dependent claims 25, 27-34 depend directly or indirectly from claim 25 and are not anticipated for the same reasons. Additionally, these claims include further limitations that provide additional features not disclosed in Kimmell as discussed above in connection with claim 1.

Respectfully submitted,

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